REMARKS

Claims 1, 6-8 and 11 are pending. Claims 2-5, 9-10 and 12-28 are canceled. Claim 1 has been amended. Support for the amendments to claim 1 can be found in the specification as originally filed, for example, in the Example on pages 17-20. No new matter has been added.

Claim rejections – 35 U.S.C. §112

Claims 1, 6-8, and 11 are rejected under 35 U.S.C. §112, first paragraph. The Office Action at page 2 acknowledges that the specification is enabling for measuring plasma concentration of ADMA in a pregnant woman at a stage of pregnancy from 23 to 25 weeks gestation. Applicants have amended claim 1 to state "measuring asymmetric dimethylarginine (ADMA) in a plasma sample taken from a pregnant woman at a stage of pregnancy from 23 to 25 weeks gestation." As acknowledged by the Office Action, claim 1 is enabled for this limitation. Therefore, Applicants believe that this rejection is overcome and respectfully request its withdrawal.

Claim rejections – 35 U.S.C. §103

Claims 1 and 7 are rejected under 35 U.S.C. §103 as obvious in view of Boger (WO 2002/14873) and Holden (Am J Obstet Gynecol. 1998; 178(3):551-6).

Neither Boger nor Holden disclose or suggest measuring ADMA in a plasma sample taken from a pregnant woman at a stage of pregnancy from 23 to 25 weeks gestation, and determining that a woman is at risk of developing pre-eclampsia or her fetus is at risk of developing IUGR if the level of ADMA in a plasma sample is greater than 1.5 μmol/L, as required by claim 1 as amended.

Boger makes no mention of measuring any level of plasma ADMA in pregnant women during any stage of pregnancy, let alone a level of 1.5 μmol/L or greater at a stage of pregnancy from 23 to 25 weeks.

Holden describes ADMA levels of pre-eclamptic patients during only the third trimester. The third trimester is outside of the 23-25 week limitation of claim 1, therefore Holden does not disclose this limitation. Moreover, Holden's disclosure of an ADMA level of 1.17 µmol/L in the third trimester does not satisfy the claimed level of 1.5 µmol/L in the claimed stage of pregnancy of 23-25 weeks. That is, a measurement 1.17 µmol/L at 23-25 weeks would not trigger a determination that a woman is at risk of developing pre-eclampsia or that her fetus is at risk of developing IUGR.

According to MPEP §2143(A), the rationale to support a conclusion that the claim would have been obvious requires that "all the claimed elements were known in the prior art." The Office Action has not satisfied this requirement. As discussed above, no combination of Boger and Holden discloses measuring ADMA in a plasma sample taken from a pregnant woman at a stage of pregnancy from 23 to 25 weeks gestation, and determining that a woman is at risk of developing pre-eclampsia or her fetus is at risk of developing IUGR if the level of ADMA in a plasma sample is greater than 1.5 µmol/L. Thus, the combination of Boger and Holden does not render the present claims obvious.

In asserting that it would have been obvious to combine the teachings of Boger and Holden to render the present claims obvious, the Office Action at pages 7-8 states that "it would have been prima facie obvious to one of ordinary skill in the art to combine the known methods of Boger and Holden to measure the ADMA level in a pregnant woman at a stage of pregnancy from 4-25 weeks and determine the level of ADMA to predict the risk of developing pre-eclampsia, particularly since both generally embraced the potential of measuring ADMA level to determine the risk of developing pre-eclampsia."

Applicants respectfully disagree. Indeed, the Office Action on page 5 rebuts Applicants' argument that claim 1 was enabled for a stage of pregnancy of 4-25 weeks by stating:

> [I]t would have required undue experimentation for one of skill in the art to make and use the invention as claimed without a reasonable expectation of success. It is apparent that underlying conditions and gestation age could greatly affect the level of plasma ADMA.

Accordingly, the disclosure of Boger combined with Holden's disclosure of measuring of ADMA levels in the third trimester does not suggest measuring ADMA levels at a stage of pregnancy of 23-25 weeks, because the Office Action has stated that this is unpredictable and without a reasonable expectation of success. Thus Applicants assert that the claims are not obvious in view of the combination of Boger and Holden. Applicants respectfully request that this rejection be withdrawn.

In view of the above, applicant believes the pending application is in condition for allowance. Applicant submits fees herewith pursuant to the Petition for Extension of Time of Three Months and the RCE. If additional fees are required, please charge our Deposit Account No. 06-2375, under Order No. HO-P03236USO from which the undersigned is authorized to draw.

Dated: March 11, 2010

Respectfully submitted,

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